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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,252	02/27/2007	Freda D. Miller	50037/003003	3359

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
10/21/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/587,252	MILLER ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *1-52,60 and 64-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-59 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/12/08, 7/16/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-68 as originally filed are currently pending. References not included with this Office action can be found in a prior action.

Election/Restrictions

Applicant's election without traverse of Group VI, claims 53-63, in the reply filed on 7/16/09 is acknowledged. Applicant's further election without traverse of the species "nestin," "p75 NTR," and "accidental injury" in the same reply is also acknowledged.

Claims 1-52 and 64-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim 60 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/16/09.

Examination on the merits will commence at this time on claims 53-59 and 61-63 ONLY, to the extent they read on the elected species where applicable.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53-59 and 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 requires providing cells that "are capable of" regenerating skin, but the claim does not rigorously require that the cells participate in the regeneration method.

Clarification is required. Because claims 54-59 and 61-63 depend from indefinite claim 53 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 59 refers to "measurable levels" of p75 NTR, but the manner of measurement is not particularly pointed out. The metes and bounds of these "levels" is therefore completely unclear. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53-57, 61, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Tankovich et al. (2000, U.S. Patent 6,050,990).

Tankovich teaches isolating skin comprising dermal papillae from a patient's own head; separating stem cells from said skin; cloning the cells (i.e., culturing them to homogeneity); and grafting the cells into incision on a desired area on said patient's own head (column 56, line 15, through column 57, line 22). The incisions made at the recipient site are reasonably interpreted as "damaged skin."

Claims 58 and 59 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tankovich et al. (2000, U.S. Patent

6,050,990) taken in light of Li et al. (2003, U.S. Patent Application Publication 2003/0077823) and Toma et al. (2001, WO 01/53461; on 7/16/09 IDS).

The teachings of Tankovich are relied upon as summarized above. Tankovich does not explicitly teach that dermal papilla and bulge area stem cells express nestin but not p75 NTR. However, Li teaches a population of stem cells in hair follicles that expresses nestin and regenerates skin (paragraphs 22, 30, and 49) and Toma teaches a population of stem cells isolated from skin that express nestin but not p75 NTR (page 18, line 20, through page 19, line 19). The reasonable inference from the combined teachings is that the stem cells of Tankovich express nestin but not p75 NTR.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' nestin-positive, p75 NTR-negative stem cell differs, and if so to what extent, from the dermal papilla cells discussed in Tankovich. The cell of Tankovich is isolated from dermal papilla, as is applicants' cell; Li teaches that stem cells isolated from hair follicle express nestin; and Toma teaches a population of skin stem cells that express nestin but not p75 NTR. The cited art taken as a whole demonstrates a reasonable probability that the cell of Tankovich is either identical or sufficiently similar to the cell in the claimed method that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known cell is not disclosed in a reference does not make that cell patentable. Applicants' stem cell possesses inherent characteristics which might not be displayed in the tests used in Tankovich. Clear

evidence that the dermal papilla stem cells of the cited prior art does not possess a critical characteristic (e.g., expression of nestin or lack of expression of p75 NTR) that is possessed by the cell in the claimed method would advance prosecution and might permit allowance of claims to applicants' method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 53-59 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al. (2000, U.S. Patent 6,050,990) taken in view of Li et al. (2003, U.S. Patent Application Publication 2003/0077823) and Toma et al. (2001, WO 01/53461; on 7/16/09 IDS).

Tankovich teaches isolating skin comprising dermal papillae from a patient's own head; separating stem cells from said skin; cloning the cells (i.e., culturing them to homogeneity); and grafting the cells into incision on a desired area on said patient's own head (column 56, line 15, through column 57, line 22).

Tankovich does not teach isolating cells that express nestin but not p75 NTR. Tankovich does not teach treating a mammal whose skin is damaged accidentally.

Li teaches a population of nestin-expressing stem cells in hair follicles that can regenerate skin (paragraphs 22, 30, and 49).

Toma teaches a population of stem cells isolated from skin that express nestin but not p75 NTR (page 18, line 20, through page 19, line 19).

A person of ordinary skill in the art would have had a reasonable expectation of success in isolating stem cells from hair follicles that express nestin but not p75 NTR and are capable of regenerating skin because Tankovich teaches that stem cells from hair follicles can regenerate skin and hair; Li teaches that stem cells from hair follicles express nestin and can regenerate skin; and Toma teaches a population of stem cells isolated from skin that express nestin but not p75 NTR. The reasonable inference from the combined teachings is that the stem cells of Tankovich express nestin but not p75 NTR.

The manner in which the skin was damaged would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Tankovich's method applies to sealing incisions made in skin with new, hair-growing

skin. An incision made deliberately is identical to one made accidentally. A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to transplant multipotent stem cells isolated from dermal papilla or hair follicles into damaged skin because Tankovich's method regenerates hair-growing skin in an incision (i.e., damage to the skin). It would have been further obvious that the stem cells employed in Tankovich's method express nestin but not p75 NTR because Li teaches that stem cells from hair follicle regenerate skin and regenerate nestin and Toma teaches a population of multipotent stem cells isolated from skin that express nestin but not p75 NTR.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with

the instant application. A copy of such copending claims is requested in response to this Office action in order to assist the examiner with double patenting analysis of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651